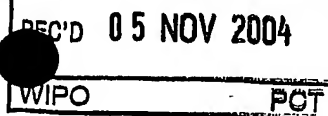


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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| | | |
|--|---|---|
| Applicant's or agent's file reference 03PCP0010 | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/KR2003/001308 | International filing date (day/month/year) 02 JULY 2003 (02.07.2003) | Priority date (day/month/year) 02 JULY 2002 (02.07.2002) |
| International Patent Classification (IPC) or national classification and IPC IPC7 C07K 14/59 | | |
| Applicant NEXGEN BIOTECHNOLOGIES, INC. et al | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:
- I ☒ Basis of the report
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

| | |
|--|--|
| Date of submission of the demand 02 FEBRUARY 2004 (02.02.2004) | Date of completion of this report 26 OCTOBER 2004 (26.10.2004) |
| Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140 | Authorized officer PARK, JEONG UNG Telephone No. 82-42-481-8159  |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/KR2003/001308

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement) under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language English which is

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☒ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheet _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed." and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION

International application No.

PCT/KR2003/001308

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

| | | |
|-------------------------------|-------------|-----|
| Novelty (N) | Claims 1-10 | YES |
| | Claims None | NO |
| Inventive step (IS) | Claims 1-10 | YES |
| | Claims None | NO |
| Industrial applicability (IA) | Claims 1-10 | YES |
| | Claims None | NO |

2. Citations and explanations (Rule 70.7)

The present invention relates to a method for preparing transformed plants expressing thyroid stimulating hormone receptor (TSHR) or thyroid stimulating hormone receptor extracellular domain (TSHR-ECD).

The following documents have been considered for the purpose of this report:

D1: Biotechnology Progress 16(5): 703-709 (2000)

D2: EP 0719858A2 (Mar. 07, 1996)

1. Novelty

D1 describes the development of a serum-free process of TSHR based on a stable transformed and highly productive human leukemia cell line K562. D2 discloses a myeloma cell line expressing recombinant human thyroid stimulating hormone (TSH), and a method for producing a membrane fraction containing recombinant human thyroid stimulating hormone receptor (TSHR). The method for preparing TSHR or TSHR-ECD by transformed plant cells is not disclosed in any of the prior art. Therefore, the subject-matter of claims 1-10 is considered to be novel under PCT Article 33(2).

2. Inventive Step

The prior art does not teach or suggest the preparing method of TSHR or TSHR-ECD by transformed plant cells. Therefore, the subject-matter of claims 1-10 is considered to involve an inventive step under PCT Article 33(3).

3. Industrial Applicability

The subject-matter of claims 1-10 is considered to be industrially applicable under PCT Article 33(4).